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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,807	10/23/2000	Gregory R. Mundy	432722002623	3395

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/695,807

Applicant(s)
Mundy et al.

Examiner
Ralph Gitomer

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 18, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) 25-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other: _____

Claims 1-43 are currently pending in this application,
claims 1-24 are considered here. The election in Paper No. 10 is
to the species of bone formation. An IDS received 7/16/01 has
not been considered because none of the references are found in
the file. The IDS received 1/23/02 has been considered to the
extent that the references are included. Priority is granted to
7/10/1998. Please update the specification regarding related
applications. The specification contains application numbers,
such as on page 34 line 2, that are unavailable to the public.
This is improper.

Applicant's election with traverse of Group I, claims 1-24,
in Paper No. 10 is acknowledged. The traversal is on the
ground(s) that Group IV should be combined with Group I. This is
not found persuasive because the methods of Groups I and IV are
separate and distinct and require entirely different issues to be
addressed in their search and consideration.

The requirement is still deemed proper and is therefore made
FINAL.

Upon resolution of the following issues, consideration
regarding double patenting and prior art may be addressed.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

5 The oath or declaration is defective because:

The full name of each inventor (family name and at least one given name together with any initial) has not been set forth. See G. Rossini.

10 Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

15 Present claim 1 is directed to a method that involves inhibiting proteasomal activity with a compound that does not inhibit the isoprenoid pathway. No mention is made in the specification as originally filed of a compound that does not inhibit the isoprenoid pathway nor how to find such a compound.

20 The specification as originally filed teaches how to determine if a compound inhibits proteasomal activity and if it is likely to enhance bone formation. However, the claims are not limited to the compounds described to do so in the specification and it would require undue experimentation to determine what
25 compounds would work in the claimed invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for three compounds described in the specification that induce bone growth, PSI, MG-132 and epoxomicin, but does not reasonably provide enablement for ~~the~~ a compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 1 the terms "a compound" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such compound would work in the instant invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of compounds.

8. The level of one of ordinary skill in this art is variable.
In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

5

Claim 18 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

10

In claim 18, the abbreviations should be spelled out fully in the first occurrence in the claims.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

15

The Abstract of the Disclosure is objected to because of legal phraseology. Correction is required. See M.P.E.P. § 608.01(b).

20

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:
Mundy (6,410,512 and 6,462,019) are directed to inhibitors of proteasomal activity and are related patents.

25

Serial No. 09/695,807
Art Unit 1651

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

5 The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status

10 of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business

15 Center for more information.

Ralph Gitomer

Ralph Gitomer
Primary Examiner
Group 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200